HeartKey® 2.0: Enabling EKG Everywhere

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Introduction

The proliferation of cardiovascular disease (CVD) in an ageing modern society presents a fundamental challenge to healthcare. CVDs are the leading cause of mortality worldwide, accounting for 32% (17.9 million) of global deaths in 2019.[1] Additionally, CVDs can lead to chronic disabilities that diminish a patient's quality of life and require extensive medical resources to manage. Unsurprisingly, CVDs are a tremendous, and ever-increasing, financial burden on global health.

In the US alone, it is estimated that CVDs contribute an excess of $320 billion in healthcare costs and lost productivity annually.[2]

The stress placed on healthcare by CVDs is compounded by a global shortage of medical professionals to meet the required care demands, leading to increased clinical burden and longer waiting times for patients. Patient demand had been outstripping medical resources even before the COVID-19 pandemic. Post-pandemic, the growing backlog of people awaiting medical consultation and care has exacerbated this problem, which now poses a serious future concern for patients and healthcare providers alike. As the burden on healthcare continues to rise, a clinician's time has never been more valuable. In light of these concerns, two healthcare trends have emerged to combat the burden of CVD on clinicians.

Telecardiology

Telecardiology uses electronic communication tools coupled with accessible EKG technology to allow the clinician to remotely diagnose, monitor and treat CVDs. Although remote collection of EKG data via Holter devices and subsequent interpretation by clinicians in hospital settings has been around for decades, the monumental uptake in telecardiology observed during the COVID-19 pandemic has highlighted the utility of the approach, as patients and healthcare providers sought safe ways to access and deliver healthcare. As a result, the global telecardiology market is expected to grow at a CAGR (Compound Annual Growth Rate) of 19% over the next five years.[3] Among numerous other patient benefits, telecardiology has the potential to significantly reduce consultation time, alleviating physician shortages and reducing the overall burden on the health system.

Preventative Healthcare

This approach is centred around the early detection of cardiac abnormalities, which allows the identified conditions to be promptly treated and appropriate medical precautions to be implemented. In doing so, the risk of the abnormality developing into a more serious CVD is minimized, reducing potential health risk to the individual and mitigating future burden on the healthcare system.

PREVENTATIVE HEALTHCARE IS PARTICULARLY COMPELLING FOR CVDS AS IT IS ESTIMATED THAT 80% ARE PREVENTABLE.[4]

A recent estimate has placed potential savings to the UK's National Health Service (NHS) at £30 million per year if the population-wide risk of CVD in England and Wales could be reduced by just 1%, which does not account for decreased losses in productivity and improvements in general health.[5]

Role of Emerging EKG Technology

Technological innovations continue to change the way individuals manage their health. Although the integration of consumer technology into the clinical space is still in its infancy, it is expected to play a vital role in future preventative cardiac healthcare and telecardiology applications. The potential is reflected in the 7% CAGR growth forecast of the global wearable EKG monitors market by 2025.[6]

> The ability to make a safe and accurate diagnosis from a pool of pre-existing data collected on everyday consumer devices is a transformative approach to EKG use with the potential to save time and resources for the clinician.

The ever-expanding range of EKG-functionalised consumer devices tend to have one common feature: they use dry electrodes to measure the heart's electrical signal. Although born out of necessity, dry electrode devices have numerous user benefits over the wet electrode devices traditionally used for out-of-hospital heart monitoring.

These include improved ease of use and the potential for long-term, non-obstructive EKG monitoring, which invariably leads to greater patient compliance. However, extracting diagnostic information from the raw EKG data obtained on consumer devices can be challenging for two reasons. Firstly, the increased impedance of dry electrodes results in greater noise contamination. Secondly, when the electrode-skin interface is positioned at peripheral locations on the body, such as the wrists or hands, the resulting EKG has a lower signal amplitude. Combined, these issues can produce poor-quality data in which the relevant EKG waveforms are buried under and distorted by noise artifacts.

Importance of Signal Conditioning

EKG signal conditioning is a vital processing step that allows clinicians to effectively analyze acquired EKG data. Prior to an effective signal conditioning step, the diagnostic information can be obscured by various forms of noise contamination, which necessitates costly and time-consuming repeat recordings.

An effective signal conditioning step maximizes the diagnostic value of EKG data by ensuring that the signal is of high quality, that noise artifacts are minimal, and that the morphology of EKG waveforms are readily distinguishable. In turn, this helps clinicians make more confident decisions based on better quality data, which speeds up the diagnostic pathway.

HeartKey® 2.0

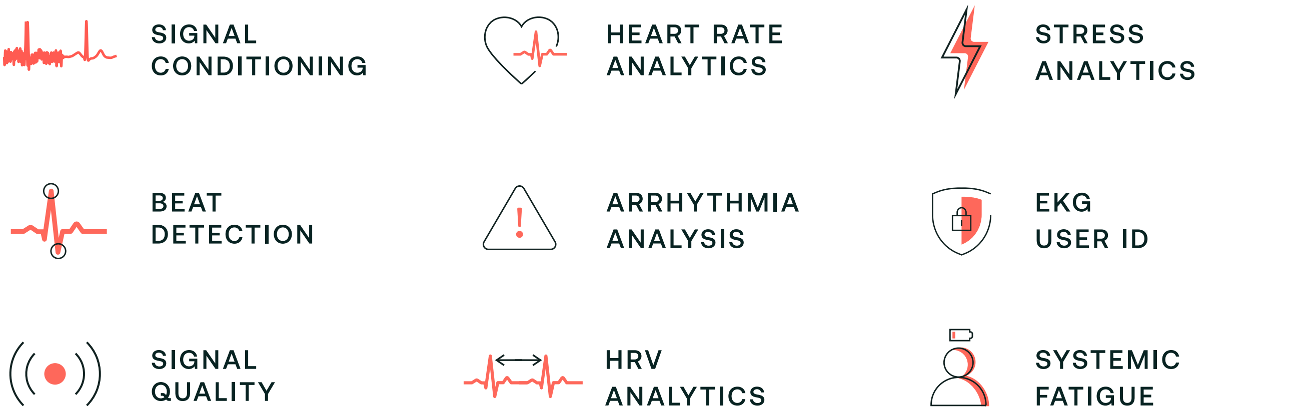


Figure 1. Overview of EKG signal processing algorithms in the HeartKey 2.0 suite.

HeartKey® 2.0 is a suite of powerful EKG signal processing algorithms capable of outputting numerous health and wellness metrics (Figure 1).

The versatility and low computational demand of HeartKey 2.0 algorithms facilitate their seamless integration into a wide variety of consumer devices, medical hardware and cloud-based platforms. This enables accurate output of EKG-based metrics in virtually any scenario.

> 'It (HeartKey 2.0) assists in identification of that diagnosis by making it much clearer to see the pattern, therefore making it more user friendly for the busy clinician.'
>
> Dr Pierre Le Page, Consultant Cardiologist

HeartKey 2.0 Signal Conditioning

Central to HeartKey 2.0's technology is an adaptive, intelligent Signal Conditioning algorithm which enables highly accurate EKG interpretation on a range of challenging use cases (Figure 2).

This capability is pivotal in facilitating the integration of consumer devices into healthcare applications and has potentially huge impacts on both preventative and proactive heart monitoring.

> 'HeartKey 2.0 takes the raw, messy dry electrode wearable data and reveals the patient's EKG data hidden within.'
>
> Dr Austin Gibbs, Associate Specialist in Cardiology

The broad range of use cases in which HeartKey 2.0 can be utilized to enable high quality data acquisition via reliable signal processing is rapidly expanding. With the wearable EKG monitors market expected to show continued growth into 2025, HeartKey 2.0 enables flexibility in the design and manufacturing of novel wearable form factors by ensuring EKG data collected from a range of body locations using multiple electrode types can be readily optimized.

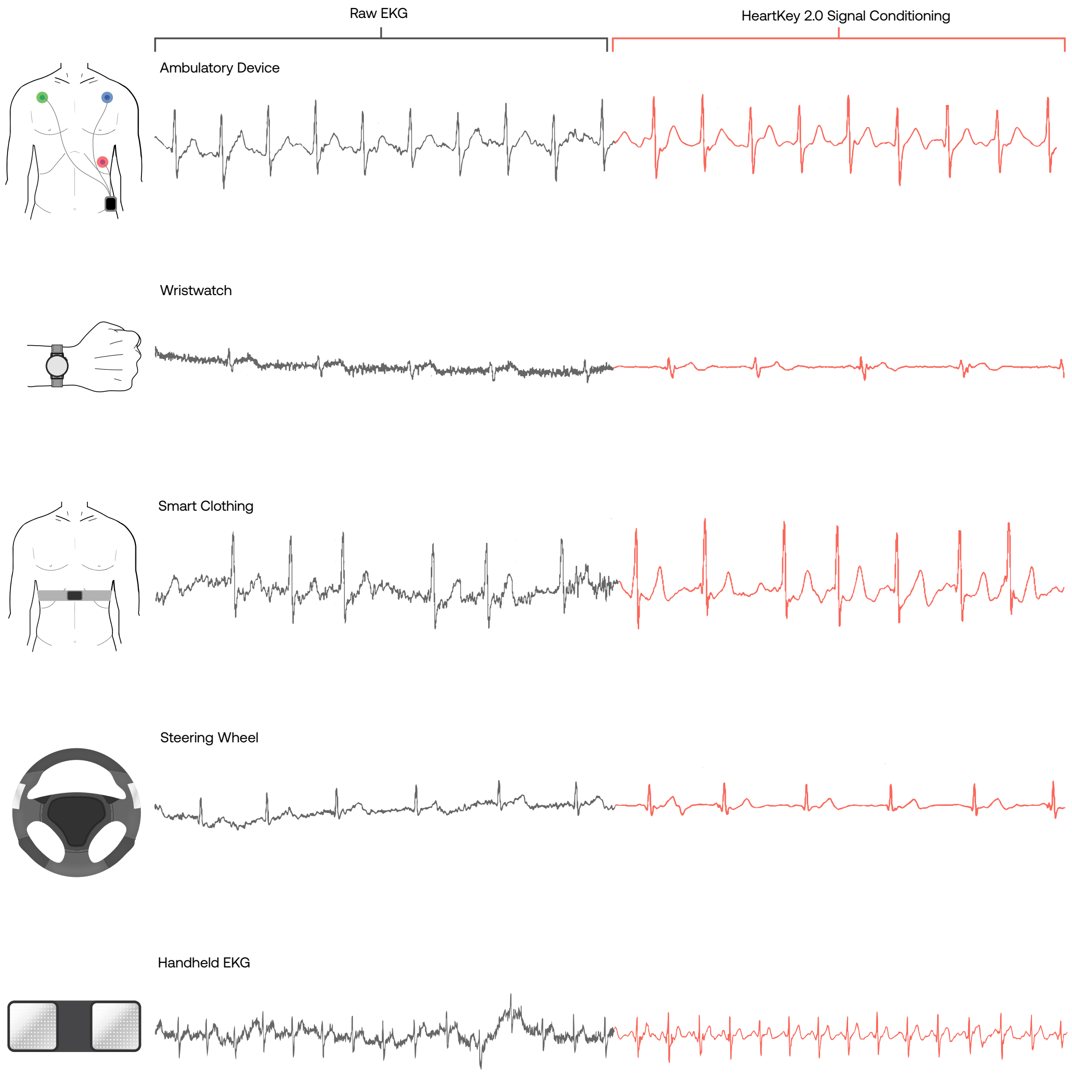


Figure 2. HeartKey 2.0 Signal Conditioning capability on a varied range of use cases.

HeartKey® 2.0

Clinical EKG Interpretation

The complex nature of EKG analysis often leads to interpretation disagreements between clinicians. While certain conditions drastically alter the characteristics of an individual's EKG, others cause only a slight deviation from a normal sinus rhythm (NSR) and are notoriously difficult to detect.

Abnormalities produced by certain cardiac diseases can also manifest in an almost identical manner, making it difficult to differentiate between them. To further complicate matters, if the acquired EKG data is of low quality, the clinician must decide whether to repeat the recording, which is both costly and time consuming, or attempt to make a diagnosis based on the poor-quality data, which risks inviting clinical error. This is particularly problematic in the context of life-threatening arrhythmias, such as ventricular fibrillation, that require immediate medical intervention. If misdiagnosed, this life-saving treatment (defibrillation) is potentially fatal.

EKG interpretation is a vital task that requires the clinician to possess extensive knowledge of cardiac anatomy, electrophysiology, and pathophysiology. In addition, the EKG interpreter must have a sharp eye for visual pattern recognition and diagnostic reasoning capability. Variations in a clinician's level of specialist training and practical experience can therefore lead to considerable ambiguity in EKG interpretation. Emergency Physicians, for instance, will have a broad medical knowledge and although they are capable of interpreting vital sign measurements, they are not generally specialized in cardiology. In contrast, a cardiologist who has spent years studying and analyzing EKG in-depth will be able to annotate to a higher degree of accuracy by picking up on features that non-specialized physicians have overlooked.

The poor agreement between physicians has been highlighted in a recent review by Cook et al.[7] By analyzing the data from 78 independent studies, they found that EKG annotation accuracy varied considerably between medical students, resident doctors, practicing physicians and cardiologists – with average accuracies of 42.0%, 55.8%, 68.5% and 74.9% respectively (Figure 3). The study emphasized that even among cardiologists with relatively similar levels of specialist EKG training, wide variability in annotation accuracy (49-92%) was observed. Overall, the results suggest that all types of physicians could benefit from additional tools to aid EKG annotation.

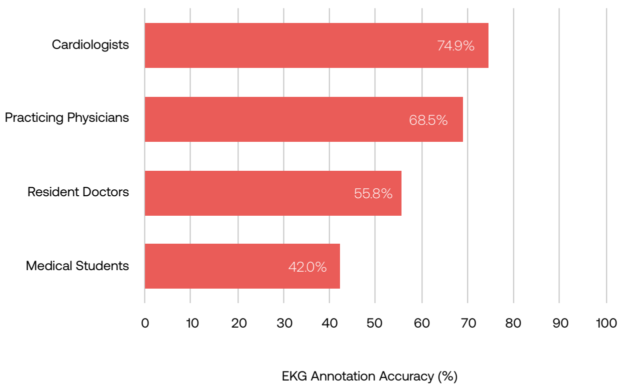


Figure 3 . Differences in average EKG annotation accuracies between clinicians with varying levels of training.

Streamlining Clinical EKG Diagnosis with HeartKey 2.0

The presence of noise in poorly processed EKG data can diminish the signal quality and ultimately lead to misdiagnosis.

If left unchecked, noise artifacts could be mistaken for EKG waveforms and used to inform an incorrect clinical decision. Conversely, if the signal processing step removes true EKG features alongside noise, then critical physiological events could be missed, therefore delaying or preventing the diagnosis of a cardiac abnormality, with potentially life-threatening consequences. The HeartKey 2.0 Signal Conditioning algorithm successfully filters noise artifacts whilst retaining true waveform morphology, improving the readability of the EKG trace and streamlining interpretation for the clinician. In turn, this leads to a reduction in time taken to reach a diagnosis, and increases confidence in said diagnosis, as the clinician is assured of the high EKG signal quality – inevitably leading to improved patient care.

To investigate the potential impact of HeartKey 2.0 in a clinical setting, 43 challenging EKG signal strips from a proprietary Arrhythmia database (n=64) were supplied to an Associate Specialist in Cardiology with and without signal conditioning from HeartKey 2.0.

An example of the same EKG strip with and without EKG processing is shown below, alongside the clinician's comment on certainty of diagnosis (Figure 4).

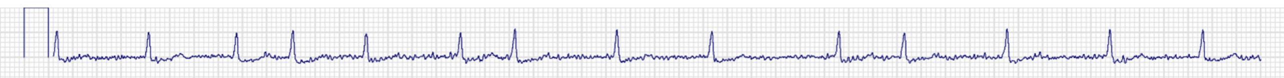
The clinician then provided an opinion score regarding the impact of HeartKey 2.0 Signal Conditioning on the diagnosis process, based on the following three questions:

1. Could HeartKey 2.0 improve a clinician's confidence in diagnosis?
2. Could HeartKey 2.0 speed up diagnosis?
3. Could HeartKey 2.0 improve ease of EKG readability?

The clinician **agreed** or **strongly agreed** that HeartKey 2.0:

- **35%** Provided more confidence in diagnosis in 35% of EKG strips
- **37%** Sped up diagnosis in 37% of EKG strips
- **63%** Improved the ease of EKG readability in 63% of EKG strips

Raw EKG "Insufficient data to be confident in diagnosis"



Processed EKG "Atrial fibrillation"

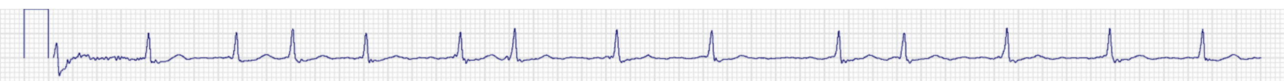


Figure 4. Example EKG strip provided to the interpreting clinician, pre- and post-processing through HeartKey 2.0, with clinician comments.

EKG signals processed with HeartKey 2.0 were significantly more likely to be diagnosed relative to the raw signals. The percentage of EKG signals that were deemed as 'insufficient data to be confident of the diagnosis' dropped from 42% to 7% after processing. 15 raw EKG signals that were initially deemed as 'unreadable' could be given a clinical diagnosis after processing with HeartKey 2.0. Furthermore, with a visibility of only the HeartKey 2.0 processed signal, there was a 100% agreement in diagnosis when the clinician had visibility of both raw and processed EKG data.

> "With HeartKey 2.0, demand on the resource is removed, and you can see the P waves so clearly that it's easy to be confident in the diagnosis."
> **Dr Austin Gibbs, Associate Specialist in Cardiology**

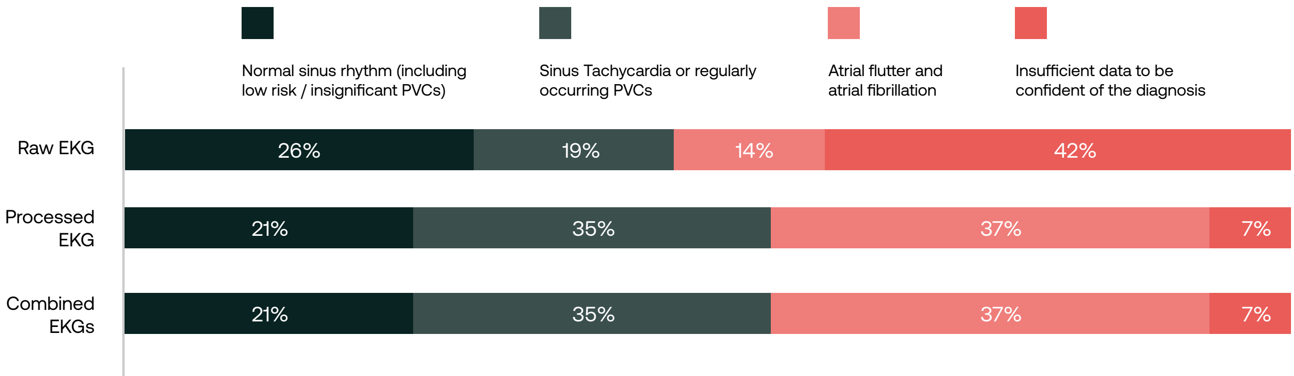


Figure 5. Diagnosis of EKG strips from arrhythmia database with a visibility of of the raw EKG, HeartKey 2.0 processed EKG signal, and with both.

QRS Peak Detection

As part of the Signal Conditioning package, HeartKey 2.0 also features a QRS Peak Detect algorithm that serves as the foundation from which more complex HeartKey algorithms, such as Arrhythmia Analysis, are developed. To validate HeartKey 2.0's Peak Detect capability, the full arrhythmia database (n=64) was processed through HeartKey 2.0's Signal Conditioning algorithm. Each individual record was annotated by trained personnel and the performance statistics were generated against these annotations.

> HeartKey 2.0 demonstrated highly accurate QRS detection on this challenging arrhythmia database, with an average QRS sensitivity of 99.20% and positive predictive value of 98.40%.

In summary, by using HeartKey 2.0 to effectively process clinical EKGs, the amount of useable data is significantly increased, allowing clinicians to make confident diagnoses without the need for repeat investigations, which reduces the clinical burden.

Case Study 1

The use of Virtual Reality and Continuous Stress Monitoring to Reduce Pain, Anxiety and Acute Complications during Pacemaker Insertion

Background

Accurate monitoring of physiologic variables during surgical procedures is vital for managing patient anxiety, pain levels, and degree of sedation. For pacemaker insertions and revisions, which are performed under local anesthetic with minimal sedation, this is particularly important.

Increased levels of anxiety during pacemaker procedures are linked to a higher degree of intraoperative patient movement that increases the likelihood of medical complications, such as lead dislodgement, pocket hematoma and pneumothorax, among others.

To combat this, patients receive greater levels of propofol to induce deeper sedation. This poses inherent health risks in itself, including over-sedation, hypotension, airway obstruction, and apnea. Diverting the patients' attentional capacity away from the procedure using Virtual Reality (VR) headsets has recently been reported to reduce both pain and anxiety levels.[8]

This leads to less patient movement, a reduction in the intraoperative doses of analgesics and sedatives, and therefore reduced complication rates.

Figure 6. Patient undergoing pacemaker insertion with VR headset, with clinician using HeartKey 2.0 to continuously monitor patient's Heart Rate Variability (HRV) and stress.

Methods

To evaluate the effectiveness of VR technology in inducing relaxation during pacemaker insertion, patients were fitted with a wet-electrode EKG chest module and continuously monitored throughout the procedure.[9] The raw EKG data was streamed live through the HeartKey 2.0 algorithm suite. Heart Rate (HR) and Heart Rate Variability (HRV) metrics were used by the HeartKey 2.0 Stress algorithm to generate an overall stress score as a percentage relative to baseline measurements, alongside an indicator of stress state – Recovery, Low, Medium, High.

The HeartKey 2.0 Stress outputs can be used to quantify the patient's overall pain and anxiety levels, helping the clinician to make an appropriate decision regarding medication. An example of live feedback HR and Stress Score feedback from one patient is shown in Figure 7.

Before pacing, HRV derived stress score was zero. Despite the use of only local anesthetic at the incision site with no sedation or IV analgesia, the patient immersed in the VR environment reported being unaware of the procedure, which is reflected by the low stress score.

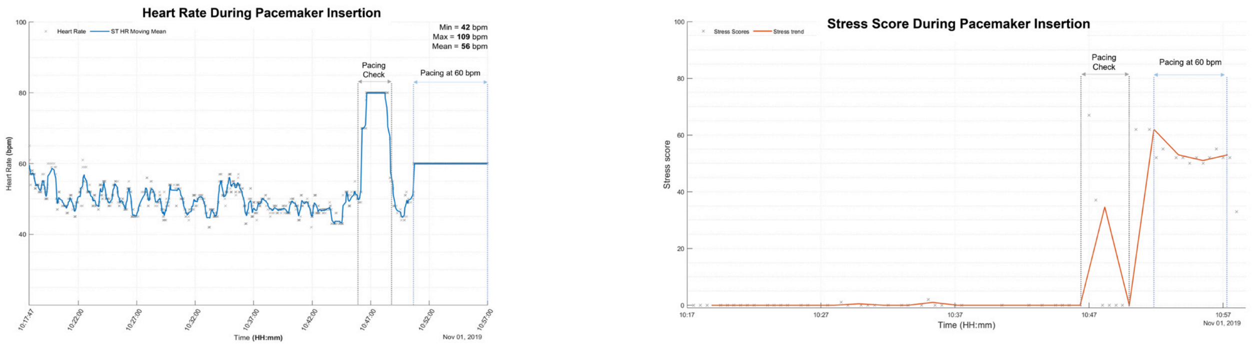


Figure 7. Live feedback of Heart Rate and Stress Score outputs during pacemaker insertion.

Results

HeartKey 2.0 HRV analytics confirmed a return to normal heart rhythm after pacemaker insertion (Figure 8). Relative to those that underwent the procedure without VR, a greater reduction in post-procedure State-Trait anxiety and Visual Analogue pain scores were recorded for the patients that were immersed in VR, which coincided with the lower levels of physiological stress measured by HeartKey 2.0 throughout the procedures. Lower levels of analgesics and sedatives were required overall when VR was used. In several cases, no sedation at all was required. While the small size of the study prevents any definitive conclusions from being drawn regarding surgical complications, the procedures themselves were described as more straightforward by the performing clinician.

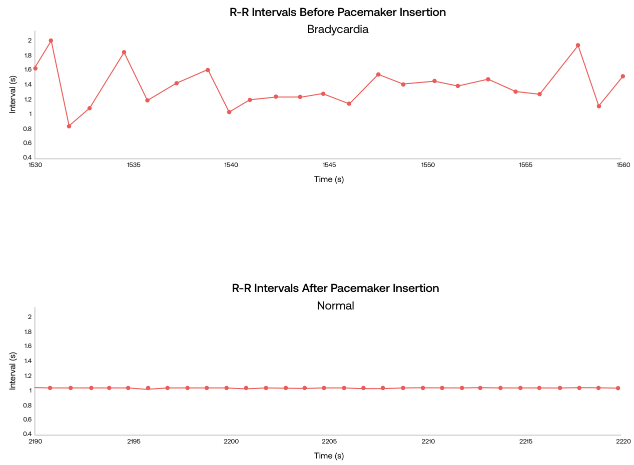


Figure 8. HeartKey 2.0 R-R interval output showing restoration of normal heart rhythm after pacemaker insertion.

Case Study 2

The use of Arrhythmia Detection Algorithms to Classify Regular and Irregular Cardiac Rhythms before, during and after Direct Current Cardioversion Procedures

Background

Computational programs that interpret and autonomously diagnose cardiac arrhythmias are powerful tools to aid clinical diagnosis.

HeartKey 2.0 features an FDA 510(k) cleared Arrhythmia Check algorithm capable of detecting and classifying the cardiac rhythm as: normal, bradycardia, tachycardia, atrial fibrillation or inconclusive. Automated arrhythmia detection algorithms have clear value for the detection of arrhythmias, such as atrial fibrillation, using screening approaches. Although less obvious, numerous clinical scenarios can also benefit from additional tools to aid in cardiac rhythm identification.

An example of a clinical scenario that could benefit from HeartKey 2.0's Arrhythmia Check is the Direct Current Cardioversion (DCC) procedure.

DCC is used to restore normal sinus rhythm via the administration of an appropriately timed electric shock to the heart, for patients presenting with a range of cardiac arrhythmias including atrial fibrillation, atrial flutter and left ventricular failure, among others. Although the initial cardioversion shock is usually successful (>90%), in some cases, higher energy repeated DCC is required to restore NSR.[10] Additionally, the heart may revert to AF in as little as a few minutes after the procedure, which may then have to be repeated. It is therefore beneficial to include an AF detection output that can quickly and confidently inform the clinician whether a normal rhythm has been restored and that the procedure was successful, or whether the patient still exhibits an abnormal rhythm and requires additional shocks.

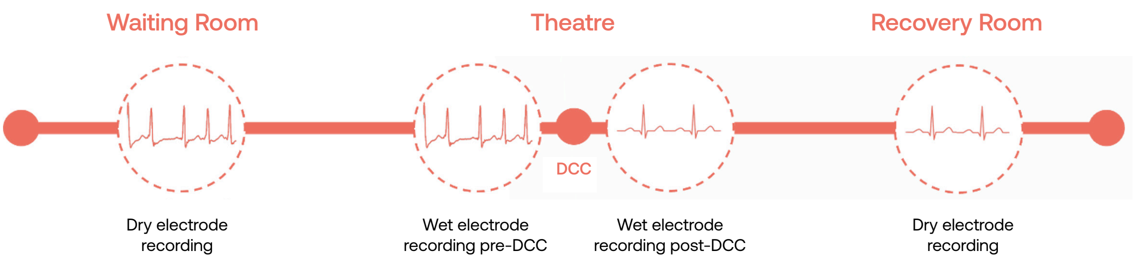


Figure 9. Outline of EKG Recordings taken throughout DCC procedure.

Methods

Patients presenting with a range of cardiac arrhythmias including atrial fibrillation, atrial flutter, and left ventricular failure, were offered medical intervention via DCC at the Jersey General Hospital. On arrival to the hospital waiting room, patients had an initial 30 second spot check EKG recording performed using a dry electrode handheld EKG data logger. Data was live streamed to the accompanying HeartKey 2.0 app, where the Arrhythmia Check algorithm returned a rhythm output (normal, bradycardia, tachycardia, atrial fibrillation or inconclusive). In theatre, an EKG recording was performed prior to and immediately after DCC using a wet electrode data logger. The Arrhythmia Check outputs were live streamed to the HeartKey app during each EKG recording allowing the monitoring of the patient's cardiac state throughout the procedure and confirming either successful or unsuccessful restoration of NSR. Following the procedure, a final 30 second spot check EKG recording was performed using the dry electrode handheld EKG data logger while the patient was in the recovery room (Figure 9).

Results

The HeartKey 2.0 Arrhythmia Check algorithm successfully detected atrial fibrillation prior to DCC therapy on both wet and dry electrode devices (Figure 10). After DCC, EKG data collected on devices of both electrode types confirmed the restoration of NSR, helping the clinician and the supporting theatre team to reach a clinical decision and conclude the procedure.

> 'Whilst using HeartKey in both the VR clinical trial and during Cardioversions, one of the surprising things is the staff beginning to change their clinical practice. For example, the anesthetics and theatre team will often use HeartKey's output to check if the cardioversion has been successful.'
>
> **Dr Austin Gibbs, Associate Specialist in Cardiology**

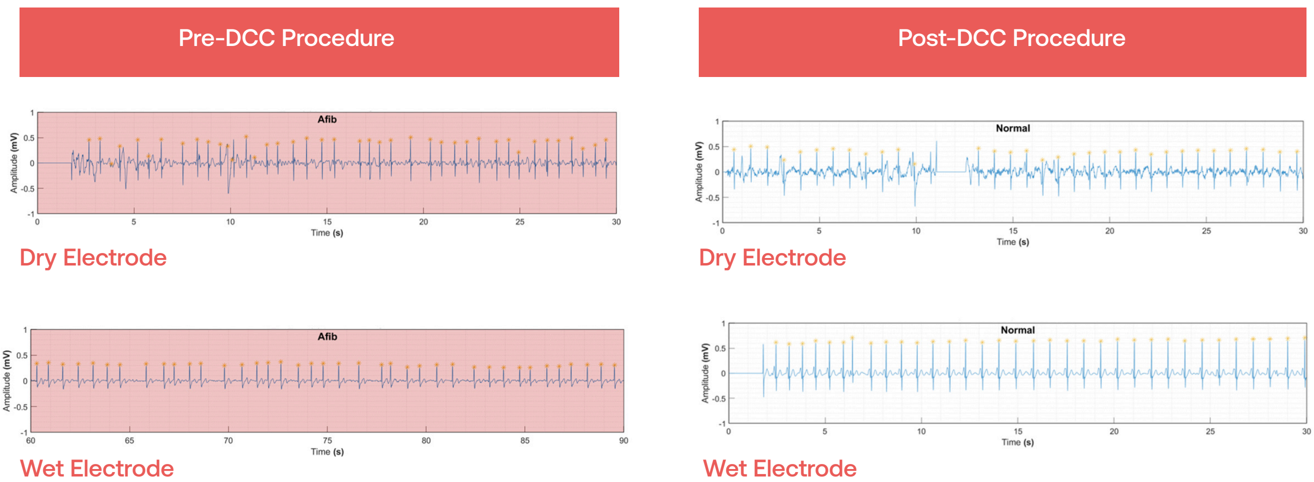


Figure 10. Confirmation of cardiac rhythm as 'atrial fibrillation' prior to DCC, and 'normal' after DCC using HeartKey 2.0 Arrhythmia Check.

Conclusion

Using its suite of EKG signal processing algorithms, HeartKey 2.0 has the potential to reduce the time taken to diagnose irregular cardiac conditions by ensuring that high-quality EKG data with minimal noise contamination is supplied to the clinician.

By utilizing HeartKey 2.0, the need for a second opinion, repeat EKG, or time resources for busy cardiac technicians to review is minimized, which could potentially lead to reduced costs, improved diagnosis time, and increased clinician confidence.

Future clinical pathways may see users collecting and owning their own EKG data, putting the power in the end user's hands to seek the relevant medical attention, allowing a more direct clinical pathway and alleviating wait times. HeartKey 2.0's versatility across a range of wet and dry electrode devices ensures high-quality signal to the clinician every time.

References

1. https://www.who.int/en/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)
2. Bellows et al. Spending on Cardiovascular Disease and Cardiovascular Risk Factors in the United States: 1996 to 2016. Circulation. 2021;144:271–282 DOI: 10.1161/CIRCULATIONAHA.120.053216
3. https://www.marketdataforecast.com/market-reports/telecardiology-market.
4. American Heart Association - CDC Prevention Programs | American Heart Association. Retrieved April 25, 2022, from https://www.heart.org/en/get-involved/advocate/federal-priorities/cdc-prevention-programs
5. Barton et al. Effectiveness and cost effectiveness of cardiovascular disease prevention in whole populations: modelling study. BMJ 2011;343:d4044. DOI: 10.1136/bmj.d4044
6. https://www.researchandmarkets.com/reports/5321405/wearable-EKG-monitors-global-market-report-2021
7. Cook, D. A., et al. Accuracy of Physicians' Electrocardiogram Interpretations: A Systematic Review and Meta-analysis. JAMA Internal Medicine, 2020, 180, (11), 1461–1471. DOI: 10.1001/JAMAINTERNMED.2020.3989
8. Roxburgh, T et al. Virtual Reality for Sedation During Atrial Fibrillation Ablation in Clinical Practice: Observational Study. Journal of Medical Internet Research. 2021; 23. e26349. DOI: 10.2196/26349.
9. Gibbs, A et al. The use of Virtual Reality and Continuous Stress Monitoring to Reduce Pain, Anxiety and Acute Complications during Pacemaker Insertion. Poster presented at: 46th ISCE Annual Conference; 2022 Apr 6-10; Henderson, Nevada (NV). In press.
10. Kirchhof, P, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS. Europace 2016; 18:1609–7. **DOI: 10.1093/eurheartj/ehw210**

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